REMARKS IN RESPONSE TO RESTRICTION REQUIREMENT

Examiner stated that Group I (Claims 1-2, solution containing calcitonin, class 530, subclass 200+) and Group II (Claims 3-7, method of administration of calcitonin, class 530, subclass 200+) are related as product and process of use. Examiner further suggested that because calcitonin can possibly be administered orally and does not require the claimed intranasal administration, it can be used in a materially different process than that of Claims 3-7, therefore Group I and Group II are distinct. Examiner also noted that process claims that include all the limitations of a patentable product are rejoined as a matter of right to the product claims. Lastly, Examiner noted that the burden of searching "databases for foreign references and literature searches" might be increased were Claims 1-7 to be considered together.

Applicant respectfully traverses the restriction requirement because Claims 1-2 encompass a novel calcitonin solution that is expressly limited to intranasal administration and therefore does not have use in a process other than that of Claims 3-7. In particular, in contrast to Examiner's suggestion, the solution of Claims 1-2 is neither claimed nor described as being suitable for oral administration. Thus, this basis for the proposed Restriction requirement is insufficient. *See Caterpillar Tractor Co. v. Comm'r of Patents & Trademarks*, 650 F. Supp. 218, 231 U.S.P.Q. 590 (E.D. Va. 1986).

Further, process Claims 3-7 do expressly include *in ipsis verbis* all the limitations of product Claims 1-2. Each of Claims 1-2 as well as Claims 3-7 encompass a novel combination of ingredients to provide a useful calcitonin formulation for intranasal administration which can be delivered to an individual. Because the language of Claims 3-7 recites and incorporates exactly all the limitations of Claims 1-2, Claims 3-7 can be rejoined as a matter of right to the product Claims 1-2.

Moreover, Examiner's search burden is not increased by considering Claims 1-7 together. Importantly, Examiner identified all of Claims 1-7 as belonging to the same class 530. Thus, on that basis the search burden is the same. In addition, because the same "databases for foreign references and literature searches" would be used for each of Claims 1-2 and Claims 3-7, the search burden is the same. In fact, the field of search for Claims 1-2 as well as Claims 3-7 is the same, namely, to locate references pertinent to a novel calcitonin solution for intranasal

administration. In sum, Examiner's search burden is not increased by considering Claims 1-7 together.

In conclusion, Applicant respectfully requests that the proposed restriction requirement be withdrawn and request reconsideration of pending Claims 1-7.

Provisionally, in the event the restriction requirement is maintained despite the foregoing discussion, Applicant elects Group I with traverse for the reasons stated above. In addition, Applicant suggests that it is amenable to withdrawing the traverse should Examiner agree that Claims 3-7 would be rejoined and allowed to issue upon the examination and allowance of Claims 1-2.

If any claims have been considered withdrawn, Applicant asserts that the withdrawal was without prejudice and without waiver of any right to pursue prosecution of the withdrawn subject matter in a separate patent application, or to seek rejoinder of the withdrawn claims in the present application.

Should there remain any unresolved issue that would require an adverse action, it is respectfully requested that Examiner telephone Applicant's attorney so that such issue may be resolved as expeditiously as possible.

Respectfully submitted,

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